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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,660

04/13/2004

Robert N. Kortzeborn

4347

8861

7590

10/16/2008

Harris Zimmerman  
Law Offices of Harris Zimmerman  
Suite 710  
1330 Broadway  
Oakland, CA 94612

EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

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3763

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,660	<b>Applicant(s)</b> KORTZEBORN, ROBERT N.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,9,10 and 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This is the second Office Action based on the 10/728660 application filed April 13, 2004.

Claims 1, 2, 9, 10, and 16-18 as amended are currently pending and considered below.

#### ***Response to Amendment***

1. In light of amendments made by the applicant to the drawings and specification, the examiner hereby withdraws all previous objections to the drawings and specification.

#### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities: the final line on page 1 of the claims ends in a period -- . -- but it is not the end of the claim, which continues with two lines on page 2. Claim 1 should be written as a single sentence. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 18 contains the phrase "each secured to a respective body" which, as presented, incorporates a human or animal body into the claim.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPGPub 2002/0038101 A1 to Avrahami et al in view of USPGPub 2002/0058902 A1 to Kollias et al and in further view of USPN 5,455,864 to Park.

Regarding claim 1, Avrahami et al teach a transdermal patch for delivery of a bio-active agent into the skin of a living body which patch is fastenable to a surface of the skin, the patch containing at least one agent storage pad positioned to dispense agent into the skin (308) and containing electrically operated driver means (370) for causing delivery of the stored agent from the storage pad into the skin and containing a battery (354) for supplying electrical current to the driver means, further including: a programmable digital data processor (360) controlling dispensing of said agent by said reservoir pad and driver means, an analysis unit (372) for sensing the concentration of a

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substance in the body, including means for extracting a fluid sample from the skin (Paragraph [0051]) [...] and providing said concentration signals to said digital data processor enabling dispensing of said agent into the skin when said concentration is outside of a particular range of concentrations (Paragraph [0212]), further including a radio receiver (Paragraph [0045]; "other wireless [...] data port" can include radio port, additionally if the device receives information it must have a receiver) [...] said programmable digital data processor and said analysis unit being contained within said patch (350).

However, Avrahami et al do not explicitly teach or disclose that the analysis unit has an IR source and detector, or that the device transmits information using encrypted radio signals.

Kollias et al teach an analysis unit which uses reverse iontophoresis in order to extract a fluid sample from the skin and uses infrared spectrophotometry (and therefore an emitter and a detector) in order to analyze certain biological substances in the interstitial fluid (Paragraphs [0037], [0038], and [0040]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the analysis unit of Kollias et al in the analysis and delivery unit of Avrahami et al because substances have unique IR spectra and it would therefore be an easy way to identify compounds in the extracted body fluid.

Park teaches a method for encrypting radio signal transmissions and de-encrypting them on the receiving end for use (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to encrypt the

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radio signals sent between the location spaced apart from the patch and the patch itself of Avrahami et al and Kollias et al with the method of Park in order to ensure the patch could not accidentally be activated by another source or to secure private data transmitted to the location (Col. 1, line 62-Col. 2, line 2).

Regarding claims 2, 9, and 10 Avrahami et al further teach that the patch contains a plurality of said agent storage pads each storing a different agent, further including a plurality of said electrically operated driver means each being operative on a separate one of said plurality of agent storage pads in response to actuating signals from said data processor (Paragraph [0226]). Further, Avrahami et al teach an internal radio transmitter for transmitting encrypted radio signals indicative of said concentration of said substance (336) to a location which is spaced apart from said patch (Paragraph [0230]), said internal radio transmitter being contained within said patch (350) and a remote radio transmitter and receiver situated apart from said patch and being conditioned to transmit said programming signals as encrypted radio signals to said internal radio transmitter and receiver and to receive said encrypted radio signals indicative of said concentration of said substance (Paragraph [0230]).

7. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPGPub 2002/0038101 A1 to Avrahami et al in view of USPN 5,455,864 to Park.

Regarding claim 16, Avrahami et al teach a transdermal patch for delivery of a bio-active agent into the skin of a living body which patch is fastenable to a surface of the skin, the patch containing at least one agent storage pad positioned to dispense agent into the skin (308) and containing electrically operated driver means for causing

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delivery of the stored agent from the storage pad into the skin (370) and containing a battery (354) for supplying electrical current to the driver means, further including: a programmable digital data processor controlling dispensing of said agent by said reservoir pad and driver means (360), and a radio receiver [...] which are input to said programmable digital data processor (Paragraph [0229]), said programmable digital data processor and said radio receiver being contained within said patch (350).

However, Avrahami et al do not explicitly teach or disclose using encrypted radio signals. Park teaches a method for encrypting radio signal transmissions and de-encrypting them on the receiving end for use (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to encrypt the radio signals sent between the location spaced apart from the patch and the patch itself of Avrahami et al with the method of Park in order to ensure the patch could not accidentally be activated by another source or to secure private data transmitted to the location (Col. 1, line 62-Col. 2, line 2).

Regarding claim 17, Avrahami et al further teach a remote radio transmitter for transmitting said programming signals as encrypted radio signals to said radio receiver (366), said radio transmitter being at a location which is spaced apart from said patch (350).

Regarding claim 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to enable several devices to be activated at one time to, for example, deliver various drug cocktails to a patient which can not be mixed prior to delivery, since it has been held that mere duplication of the essential

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working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1, 2, 9, 10, and 16-18 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763